



FH

**STATE OF WISCONSIN
Division of Hearings and Appeals**

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

DECISION

MPA/168906

PRELIMINARY RECITALS

Pursuant to a petition filed September 21, 2015, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Health Care Access and Accountability in regard to Medical Assistance, a hearing was held on October 14, 2015, at Kenosha, Wisconsin.

The issue for determination is whether the Department of Health Services, Division of Health Care Access and Accountability correctly denied the Petitioner's request for prior authorization of modafinil to treat idiopathic hypersomnia.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, Wisconsin 53703

By: OIG by letter

Division of Health Care Access and Accountability
1 West Wilson Street, Room 272
P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:

Mayumi M. Ishii
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner is a resident of Kenosha County.

2. Petitioner is 17 years-old with a diagnosis of idiopathic hypersomnia associated with excessive daytime sleepiness. (Exhibit 3)
3. Petitioner has not been diagnosed with narcolepsy, sleep apnea, shift work sleep disorder, nor ADD or ADHD. (Testimony of Petitioner's mother)
4. On August 26, 2015, [REDACTED] Pharmacy, on behalf of the Petitioner submitted a prior authorization request for 1 dose daily of modafinil, for one year, at a cost of \$10,501.08. (Exhibit 3)
5. In support of its request, the pharmacy submitted an UpToDate article from [REDACTED] indicating that the causes of idiopathic hypersomnia are unknown, so treatment is generally focused on treating the symptoms of the condition. The article goes on to state that, "Pharmacologic approaches are derived from experience with medications to treat excessive daytime sleepiness (EDS) associated with narcolepsy (table 4); supporting data in idiopathic hypersomnia are limited to case reports, retrospective series, and one small randomized trial [3,19-22]. Treatment options include modafinil, armodafinil, methylphenidate, and amphetamines. Of these, we suggest modafinil as a first-line therapy, in part because it appears to have a better side effect profile than other stimulants." (Exhibit 3)
6. The pharmacy also submitted an article from the journal Sleep, Vol. 30, No. 12, 2007, which indicated that modafinil might be effective for treatment of daytime sleepiness due to idiopathic hypersomnia and is therefore, an "option". The article further indicated that, "One level 4 study that included 24 patients with narcolepsy and 18 with idiopathic hypersomnolence examined the efficacy of modafinil in adults with idiopathic hypersomnia. There were improvements in the mean number of drowsy episodes and sleep attacks as recorded in sleep diaries for both patient groups on this medication. This is a new recommendation." (Exhibit 3)
7. On September 1, 2015, the Department of Health Services (DHS) sent the Petitioner and the pharmacy notices advising them that the request for modafinil had been denied. (Exhibit 3)
8. The Petitioner's mother, on his behalf, filed a request for fair hearing that was received by the Division of Hearings and Appeals on September 25, 2015. (Exhibit 1)

DISCUSSION

The Department of Health Services sometimes requires prior authorization to:

1. Safeguard against unnecessary or inappropriate care and services;
2. Safeguard against excess payments;
3. Assess the quality and timeliness of services;
4. Determine if less expensive alternative care, services or supplies are usable;
5. Promote the most effective and appropriate use of available services and facilities; and
6. Curtail misutilization practices of providers and recipients.

Wis. Admin. Code § DHS107.02(3)(b)

In determining whether to approve or disapprove a request for prior authorization, the department shall consider:

1. The medical necessity of the service;
- 2. The appropriateness of the service;**
3. The cost of the service;
4. The frequency of furnishing the service;
5. The quality and timeliness of the service;
6. The extent to which less expensive alternative services are available;
- 7. The effective and appropriate use of available services;**
8. The misutilization practices of providers and recipients;
9. The limitations imposed by pertinent federal or state statutes, rules, regulations or interpretations, including Medicare, or private insurance guidelines;
10. The need to ensure that there is closer professional scrutiny for care which is of unacceptable quality;
11. The flagrant or continuing disregard of established state and federal policies, standards, fees or procedures; and
- 12. The professional acceptability of unproven or experimental care, as determined by consultants to the department.**

Emphasis added. Wis. Admin. Code §DHS107.02(3)(e)

“Medically necessary” means a medical assistance service under ch. DHS 107 that is:

- (a) Required to prevent, identify or treat a recipient's illness, injury or disability; and
- (b) Meets the following standards:
 1. Is consistent with the recipient's symptoms or with prevention, diagnosis or treatment of the recipient's illness, injury or disability;
 2. Is provided consistent with standards of acceptable quality of care applicable to the type of service, the type of provider, and the setting in which the service is provided;
 3. Is appropriate with regard to generally accepted standards of medical practice;
 4. Is not medically contraindicated with regard to the recipient's diagnoses, the recipient's symptoms or other medically necessary services being provided to the recipient;
 - 5. Is of proven medical value or usefulness and, consistent with s. DHS 107.035, is not experimental in nature;**
 6. Is not duplicative with respect to other services being provided to the recipient;
 7. Is not solely for the convenience of the recipient, the recipient's family, or a provider;
 8. With respect to prior authorization of a service and to other prospective coverage determinations made by the department, is cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient; and
 - 9. Is the most appropriate supply or level of service that can safely and effectively be provided to the recipient.**

Emphasis added, Wis. Adm. Code. §DHS 101.03(96m)

Petitioner has the burden to prove, by a preponderance of the credible evidence, that the requested therapy meets the approval criteria.

Prescription drugs and drug products are a covered Medicaid service when properly prescribed. Wis. Admin. Code §DHS 107.10(1) Prior Authorization for prescription drugs is required for, “drugs the

department has determined entail substantial cost or utilization problems for the MA program. These drugs shall be noted in the Wisconsin Medicaid drug index...” Wis. Admin. Code §DHS 107.10(2)(d)

According to the Forward Health Provider Information issued in December 2014, No. 2014-78¹, “Prior authorization request for modafinil will only be approved for use to treat the following identified clinical conditions:

- Narcolepsy with cataplexy
- Narcolepsy without cataplexy
- Obstructive Sleep Apnea/hypopnea syndrome (OSHAS)
- Shift work sleep disorder
- Attention deficit disorder (ADD)
- Attention deficit hyperactivity disorder (ADHD)”

(Exhibit 2)

It is undisputed that the Petitioner does not have any of these diagnoses. As such, there is no legal basis upon which to find the modafinil medically necessary, as defined by Wis. Adm. Code. §DHS 101.03(96m), above.

I note that it appears that the usefulness of modafinil to treat idiopathic hypersomnia is still unproven.

The study upon which the Sleep Journal’s recommendations are based, consisted of a small randomized trial of 33 patients with idiopathic hypersomnia without long sleep time. While the results of the study were promising, it was too small a study group to conclusively prove the effectiveness of modafinil as a treatment for hypersomnia. This is likely why the article only concluded that the medication might be helpful.

The conclusions from UpToDate were also based upon limited information. The article states that, “supporting data in idiopathic hypersomnia are limited to case reports, retrospective series, and one small randomized trial [3.19-22].

Based upon the foregoing it is found that modafinil is not yet of proven medical value and is therefore, still experimental in nature. Consequently, it is not medically necessary, as that phrase is defined in Wis. Admin. Code. §DHS 101.03(96m), above.

CONCLUSIONS OF LAW

DHS correctly denied the request for prior authorization of modafinil.

THEREFORE, it is

ORDERED

The petition is dismissed.

¹ The approval criteria for modafinil can also be found under topic #16397, in the on-line provider handbook:

<https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx?ia=1&p=1&sa=48&s=3&c=345&nt=Stimulants+and+Related+Agents>

REQUEST FOR A REHEARING

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, Madison, Wisconsin 53703, **and** on those identified in this decision as "PARTIES IN INTEREST" **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Milwaukee,
Wisconsin, this 4th day of December, 2015

\sMayumi M. Ishii
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

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The preceding decision was sent to the following parties on December 4, 2015.

Division of Health Care Access and Accountability